

REQUEST FOR RECONSIDERATION

Applicant acknowledges with appreciation the Examiner's willingness to discuss the above-captioned patent application in a telephone interview with Applicants' representatives on April 22, 2003. In response to the Office Action mailed January 14, 2003, and in accordance with the Interview of April 22, 2003, Applicant hereby amends claims 1 and 26 and cancels claims 2, 13, 16, 19, 22, 25, and 28, without prejudice. Further, because Applicant's method claims, claims 41-57, are allowed, Applicant hereby adds a new claim to a bypass graft made by the method of Applicant's claim 41. Applicant respectfully requests that the Examiner enter the foregoing amendments. No new matter is added by these amendments, and the amendments are fully supported by the specification. In view of the accompanying Request for Continued Examination (RCE), Applicant respectfully requests that the Examiner reconsider the above-captioned patent application in view of the foregoing amendments and following remarks.

REMARKS

1. Rejections

Applicant acknowledges with appreciation that the Examiner has allowed claims 41-57. Nevertheless, claims 1, 2, 12, 12, 15, 16, 18, 19, 21, and 22 stand rejected under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 3,318,511 to Goldberg et al. ("Goldberg"). Further, claims 1-5, 24, 25, 27-31, and 38-40 stand rejected under 35 U.S.C. § 102(e), as allegedly anticipated by U.S. Patent No. 5,989,287 to Yang et al. ("Yang"). In view of the foregoing amendments and the following remarks, Applicant respectfully traverses.

2. The Term "Monolithic"

Applicant amends claim 1 to include the limitations of claim 2, and, thus, to define the graft as "monolithic." The term "monolithic" is repeatedly defined in Applicant's specification as "formed without intervening seams or overlap." Appl'n, Page 6, Lines 8-9; Page 6, Lines 17-19; Page 6, Lines 30-31; and Page 7, Lines 8-10. When the patentee "has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term," that term will be given the selected meaning, as opposed to its ordinary meaning. Johnson Worldwide Assoc., Inc. v. Zebco Corp., 50 USPQ2d 1607, 1610 (Fed. Cir. 1999). In such cases, the explicit definition from the specification should be read into the claims. Abbott Laboratories v. Novopharm Ltd., 66 USPQ2d 1200, 1205 (Fed. Cir. 2003); see MPEP 2106. As a

consequence of this amendment to claim 1, Applicant also amends the application by canceling claims 2, 13, 16, 19, 22, 25, and 28, without prejudice, and amends claim 26 to depend from claim 24, instead of canceled claim 25.

3. Goldberg and Yang References

Applicant maintains that these amendments overcome the anticipation rejections in view of Goldberg or Yang. Applicant claims a “monolithic” bypass graft. Goldberg describes a cannula terminated in a funnel. Referring to Goldberg’s **Fig. 2**, funnel assembly 1 is formed in mold 13 separate from cannula 2. As depicted in Goldberg’s **Fig. 1**, “funnel assembly 1 [is] mounted on a cannula tube 2. . . . The cannula 2 [sic] may be secured into connector portion 7 with cannula tip 8 abutting against shoulder 9 in a manner to provide a smooth interior passage at 10. [Goldberg] prefer[s] to use a silicone cement 11 to join the tube 2 to the funnel assembly.” Goldberg, Column 3, Lines 51-65. Even if funnel assembly 1 and cannula 2 are joined together with silicone or the like, Goldberg’s apparatus is formed with a seam between cannula tip 8 and funnel assembly shoulder 9, and connector 7 of funnel assembly 1 overlaps cannula 2, as well as a portion of funnel assembly 1. In view of Applicant’s amendment to claim 1, Applicant maintains that the claimed invention is distinguished over Goldberg’s apparatus.

Yang describes the addition of support sleeves 26a and 26b to each end of host vessel 22, such as a harvested vein or artery. Referring to Yang’s **Fig. 1C**, the ends of host vessel 22 are joined to a pair of a patient’s vessels to form a bypass, and support sleeves 26a and 26b are connected to the pair of vessels over the opposite ends of the host vessel 22. Yang, Column 6, Lines 32-50. Support sleeves 26a and 26b may be slipped over ends 36 and 38 of host vessel 22 and attached, e.g., by stitching, thereto. Id. Alternatively, support sleeves 26a and 26b may be attached, e.g., by stitching, end-to-end to ends 36 and 38 of host vessel 22. Id. In the first configuration, there clearly is an overlap between host vessel 22 and support sleeves 26a and 26b. In both configurations, however, there clearly is a seam between the dissimilar materials of host vessel 22 and support sleeves 26a and 26b. See Yang, Column 5, Lines 64-67, and Column 6, Lines 1-6. In view of Applicant’s amendment to claim 1, Applicant maintains that the claimed invention is distinguished over Yang’s apparatus.

Therefore, in view of the foregoing amendments and remarks, Applicant respectfully traverses the anticipation rejections based on Goldberg and Yang. Applicant respectfully requests that the Examiner withdraw those rejections.

4. Hanhk and Marcade References

During the Interview between the Examiner and Applicant's representative, the Examiner raised the possibility that either U.S. Patent No. 5,922,029 to Hanhk et al. ("Hanhk") or U.S. Patent No. 5,683,449 to Marcade, or both, might render the amended claim 1 unpatentable. Nevertheless, at the time of the Interview, the Examiner did not raise a specific anticipation or obviousness rejection based in whole or in part on either reference. Applicant now has reviewed these references, and Applicant believes that the amended claims are distinguishable over these cited references.

In Hanhk's **Fig. 1**, a conical stent 1 is disclosed which comprises a proximal segment 7, a distal segment 8, and an intermediate segment 15. Intermediate segment 15 is conical, but proximal segment 7 and distal segment 11 are depicted as cylindrical. Hanhk, Column 6, Lines 6-14. Proximal segment 7 and distal segment 11 may be of shapes other than cylindrical, and Hanhk notes that in an embodiment, the proximal end of proximal segment 7 or the distal end of distal segment 11 may be "flared up." Hanhk, Column 3, Lines 46-49. Nevertheless, the shapes of Hanhk's stents are dictated by its stent's purpose. According to Stedman's Medical Dictionary, a stent is "[a] thread, rod, or catheter, lying within the lumen of the tubular structures, used to provide support during or after their anastomosis, or to ensure patency of an intact but contracted lumen." Stedman's Medical Dictionary 1696 (27th ed. 2000) (emphasis added, copy enclosed). Thus, any "flaring" of the ends of the proximal and distal segments of the stent are intended to better anchor the stent within the lumen. Hanhk, Column 3, Lines 46-49 ("And to provide a further safety anchor . . . "). Because the stent lies within the lumen and is not adapted to join vessels as is Applicant's bypass graft, Applicant maintains that the flaring of the ends of the proximal and distal segments of Hanhk's stent does not disclose "a circumferential skirt for surgical attachment of [Applicant's] graft to a patient's blood vessel," as described in Applicant's claim 1.

As amended, Applicant's claimed invention is readily distinguishable over Marcade on at least two grounds. First, like Hanhk, Marcade describes a stent for repairing a patient's vessel from within. Marcade states that "[t]he present invention relates to bifurcated intraluminal grafts, particularly for repairing defects in arteries and other lumens within the body." Marcade, Column 1, Lines 6-8. Despite Marcade's use of the term graft, instead of stent, it is clear that unlike Applicant's invention, Marcade's graft is adapted to repair lumens from within rather than to join vessels to bypass a damaged portion. See Marcade, **Figs. 3C-3J**. Second, Marcade's system is defined as a "modular prothesis." E.g., Marcade, Column 2, Lines 19-28; Column 3, Lines 18-32 ("modular prothesis" consisting of a "base member" and a "primary tubular limb"). Specifically, Marcade states that "the term 'modular' refers to the fact that the system 100 includes a number of individual components which may be separately delivered by intraluminal techniques to the aneurysm site and then interconnected with one another in situ to form the bifurcated graft." Marcade, Column 8, Lines 63-67. Therefore, considering Marcade's system in its entirety, Applicant believes that Marcade does not disclose or suggest the monolithic graft described in Applicant's amended claim 1. See MPEP 2141.03.

Therefore, in view of at least the foregoing amendments and remarks, Applicant believes that the claimed invention is distinguishable over the disclosures of Hanhk and Marcade. Applicant respectfully requests that the Examiner allow the amended claims over these cited references.

CONCLUSION

Applicant respectfully submits that this application, as amended, is in condition for allowance, and such disposition is earnestly solicited. If the Examiner believes that an interview with Applicant's representatives, either in person or by telephone, would expedite prosecution of this application, we would welcome such an opportunity. Applicant is enclosing check including the amount for the requisite fee for a Request for Continued Examination. Nevertheless, in the event of any variance between the fees determined by Applicants and those

determined by the PTO, please charge any such variance to the undersigned's Deposit Account No. 02-0375.

Respectfully submitted,

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Enclosures

STEDMAN'S Medical Dictionary

27th Edition

Illustrated in Color



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constricting ring or shelf, or by coarctation or hypoplasia of the ascending aorta.

supravalvular s., s. distal to the aortic valve due usually to a congenital membrane. Patients usually have a kind of elfin facies and resemble each other more than they do members of their family.

tricuspid s., pathologic narrowing of the orifice of the tricuspid valve.

sten-o-ste-no-sis (sten'ō-stē-nō'sis). Stricture of the parotid duct (Steno or Stensen duct).

sten-o-sto-mia (sten-ō-stō'mē-ā). Narrowness of the oral cavity. [steno- + G. *stoma*, mouth]

sten-o-ther-mal (sten-ō-ther'māl). Thermostable through a narrow temperature range; able to withstand only slight changes in temperature. [steno- + G. *thermē*, heat]

sten-o-tho-rax (sten'ō-thōr'aks). A narrow contracted chest. [steno- + thorax]

ste-not-ic (ste-not'ik). Narrowed; affected with stenosis. SYN stenosal.

Sten-o-tro-pho-mo-nas (sten'ō-trō-fō-mōn'as). A genus of Gram-negative bacilli that typically reside in soil and water and are not a part of normal human flora.

S. maltophilia, an opportunistic ocular bacterial pathogen producing keratitis, keratopathy, and conjunctivitis; a Gram-negative non-sporebearing rod, a major emerging nosocomial pathogen, it is of especial importance in intensive care units in part because of its resistance to most penicillins and to cephalosporins and aminoglycosides. Formerly called *Xanthomonas maltophilia* and *Pseudomonas maltophilia*.

sten-ox-e-nous (sten-ok'sē-nūs). Denoting a parasite with a narrow host range; e.g., *Eimeria* (among the Coccidia), hookworm, biting and sucking lice. [steno- + G. *xenos*, a stranger, foreigner]

Stensen (Steno, Stenon, Stenonius). Niels (Nicholaus), Danish anatomist, 1638-1686. SEE *Stensen duct*, *Stensen foramen*, *Stensen plexus*, *Stensen veins*, under *vein*.

Stent, Charles R., English dentist, †1901. SEE *stent*; *S. graft*.

stent. 1. A thread, rod, or catheter, lying within the lumen of tubular structures, used to provide support during or after their anastomosis, or to assure patency of an intact but contracted lumen. 2. The process of placing a stent. 3. Device used to maintain a bodily orifice or cavity during skin grafting. 4. To immobilize a skin graft after placement. [Charles R. *Stent*]

expandable s., s. placed within the lumen of a structure, often percutaneously, that then shortens in its longitudinal dimension and increases its diameter, thereby increasing the inside dimension of the structure.

step (stēp). 1. In dentistry, a dove-tailed or similarly shaped projection of a cavity prepared in a tooth into a surface perpendicular to the main part of the cavity for the purpose of preventing displacement of the restoration (filling) by the force of mastication. 2. A change in direction resembling a stair-step in a line, a surface, or the construction of a solid body.

Krönig s.'s, extension of the lower part of the right border of absolute cardiac dullness in hypertrophy of the right heart.

Rönne nasal s., a nasal visual field defect with one margin corresponding to the retinal horizontal medium; seen in glaucoma.

ste-pha-ni-al (ste-fā'nē-āl). Pertaining to the stephanion.

ste-pha-ni-on (ste-fā'nē-on). A craniometric point where the coronal suture intersects the inferior temporal line. [G. dim. of *stephanos*, crown]

Steph-a-no-fi-lar-ia (stef'ā-fi-lār'ē-ā). A genus of Filaroid nematodes in the family Stephanofilaridae, subcutaneous parasites of large mammals, especially cattle.

S. stilesi, a skin-infecting species of filaria parasitic in cattle and transmitted by the horn fly, *Haematobia irritans*; the only species known to occur in the U.S.; characterized by a row of spines behind the mouth of the adult worm, which is 6-8 mm in the female, 2-3 mm in the male. Both adults and larvae are found in granulomatous skin lesions in cattle, usually on the underside of the abdomen. [G. *stephanos*, crown, + *filaria*]

Steph-a-nu-rus den-ta-tus (stef-ā-noo'rūs). The kidney worm or

lard worm of swine, a strongyle nematode parasite species that also occurs, though rarely, in the liver of cattle. Adult worms in swine live in the perirenal fat, the kidney pelvis, or as erratic forms in many other locations. Eggs are passed through the urine and infection is direct, by ingestion of infective larvae or by skin infection, or indirect, by ingestion of earthworms in which the larvae can survive. [G. *stephanos*, crown, + *oura*, tail]

step-page (step'aj). SYN *steppage gait*. [Fr.]

ste-ra-di-an (sr) (stē-rā'dē-ān). The unit of solid angle; the solid angle that encloses an area on the surface of a sphere equivalent to the square of the radius of the sphere. [G. *stereos*, solid, + *radion*, radius]

ster-ane (ster'an, stēr'an). The hypothetical parent molecule for any steroid hormone; a saturated hydrocarbon compound that contains no oxygen. The name was originally conceived to achieve forms of systematic nomenclature, but is now supplanted by the fundamental variants: gonane, estrane, androstane, norandrostane (etiane), cholane, cholestane, ergostane, and stigmastane. SEE ALSO *steroids*.

△ **sterc-**. Feces. SEE ALSO *copro-*, *scato-*. [L. *stercus*, excrement]

ster-co-bi-lin (ster'kō-bī'lin, -bī'lin). A brown degradation product of hemoglobin, present in the feces. SEE ALSO *bilirubinoids*.

l-ster-co-bi-lin-o-gen (ster'kō-bī-lin'ō-jen). Reduction product of *l*-urobilinogen, precursor of *l*-stercobilin in the final stages of bilirubin metabolism; excreted in feces, wherein it is oxidized to stercobilin. SEE ALSO *bilirubinoids*.

ster-co-lith (ster'kō-lith). SYN *fecalith*. [sterc- + G. *lithos*, stone]

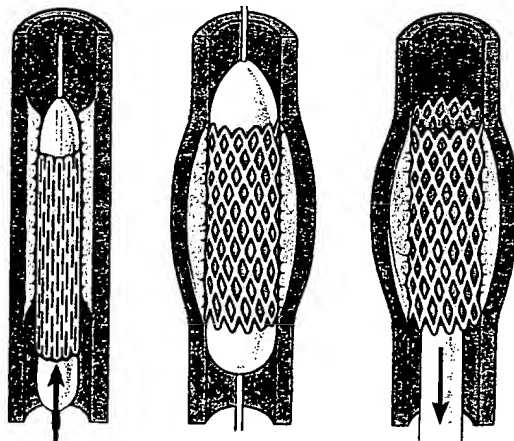
ster-co-ra-ceous (ster'kō-rā'shūs). Relating to or containing feces. SYN *stercoral*, *stercorous*.

ster-co-ral (ster'kō-rāl). SYN *stercoraceous*.

ster-co-rin (ster'kō-rin). SYN *coprosterol*.

ster-co-ro-ma (ster'kō-rō'mā). SYN *fecaloma*. [sterc- + G. *-oma*, tumor]

ster-co-rous (ster'kō-rūs). SYN *stercoraceous*.



vascular stent

ster-cus (ster'kūs). SYN *feces*. [L. *feces*, excrement]

stere (stēr, stār). A measure of capacity; equivalent to a cubic meter or a kiloliter; equal to 1.307951 cubic yards. [Fr. fr. G. *stereos*, solid]

△ **stereo-**. 1. A solid; a solid condition or state. 2. Spatial qualities, three-dimensionality. [G. *stereos*, solid]

ster-e-o-ag-no-sis (ster'ē-ō-ag-nō'sis). SYN *tactile agnosia*.

ster-e-o-an-es-the-sia (ster'ē-ō-an-es-thē'zē-ā). SYN *tactile agnosia*. [stereo- + G. *an-* priv. + *aisthēsis*, sensation]

ster-e-o-ar-thr-i-y-sis (ster'ē-ō-ar-thrō'l'i-sis). Production of a new joint with mobility in cases of bony ankylosis. [stereo- + G. *arthron*, joint, + *lysis*, loosening]

ster-e-cam-pim-e-ter (ster'ē-ō-kam-pim'ē-ter). An apparatus

for studying the fixation. [stereo- + *cam*, camera, + *meter*, measure]

ster-e-o-chem-i-c- *istry*.

ster-e-o-chem-is- *try* concerned with the study of chemical reactions in molecules, in relation to one

ster-e-o-cil-i-um, nonmotile long microorganism

ster-e-o-cin-e-flu *Obsolete practice obtained by stereoisomers*

ster-e-o-c-l-p-o-gr- *the stereocolposcopy*

ster-e-o-c-l-p-o-sc- *vides the observation of the vagina*

ster-e-o-o-cep-h- *the localization of brain*

ster-e-o-o-ec-tro- *the localization of brain*

ster-e-o-o-ec-tro- *the localization of brain*

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